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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,482	04/28/1999	NORDINE CHEIKH	04983.0031.U	4511

22930 7590 12/04/2001

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	15

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/300,482	CHEIKH ET AL.	
	Examiner	Art Unit	
	Mary Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2,10-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application contains claims 3-9 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 2 and 10-21 are under examination in this application. Claims 1 and 2 have been amended, and claims 10-21 are newly added.

Applicant's arguments filed 3/20/01 and 9/24/01 have been fully considered but they are not persuasive. Any rejections non reiterated below have been withdrawn.

35 U.S.C. 112, Written Description Rejection

Claims 1 and 2 remain rejected and new claims 10-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the disclosure of the short fragments of the claims, which are purported to encode a variety of enzymes, are an adequate written description for the claimed genus of any polynucleotide encoding the full length enzymes which may hybridize to one or more of the fragments. Applicant argues that the assertion of enzymatic activity in concert with the short fragments meets the requirements for written description. These arguments are not persuasive.

It is noted that each claimed SEQ ID NO: is not of sufficient length to encode a full length enzyme. Applicant has not even described a single full length open reading frame which actually encodes a protein having any of the asserted enzymatic activities. No protein was expressed from any fragment. No activity was assessed. Therefore, Applicant has not provided both a detailed structure of the polynucleotide nor provided any detailed functional information for any polynucleotide encoding any of the claimed enzymes.

Applicant has identified enzymes which are known in the prior art and which has a some sequence similarity to the claimed sequence. Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological and enzymatic activity of the claimed subject matter would be the

same as that of the similar sequence, let alone any undisclosed, full length sequence to be discovered later. Furthermore, it is unclear whether the similar sequence identified in the prior art has actually been tested for the biological activity or whether this also is an asserted biological or enzymatic activity based upon sequence similarity to yet a different sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. Cited previously in this regard were Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays, 18(12):973-981, 1996); Wells et al. (Journal of Leukocyte Biology, 61(5):545-550, 1997); and Russell et al. (Journal of Molecular Biology, 244:332-350, 1994). However, this level of factual evidence is absent here.

It would be impossible for one of skill in the art to determine what similar sequences would actually encode any functional enzymes from the limited information of the instant disclosure.

The claims are still directed to encompass gene sequences (genomic DNA comprising introns, exons, etc.), sequences that hybridize to SEQ ID NO: 1, 4, 14, 27, 225, 298, 311, 356, 569 and 619, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, so forth. Genomic DNA would most certainly hybridize to the short fragments of the claims, as would many allelic or splice variants, mutants, truncations, etc. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Therefore, only SEQ ID NO: 1, 4, 14, 27, 225, 298, 311, 356, 569 and 619 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Double Patenting

Claims 1 and 2 and new claims 10-21 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims drawn to polynucleotides of copending Application No. 09/304,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 66502 of the '517 application appears to encode the same enzyme as SEQ ID NO: 1 of the instant application. SEQ ID NO: 181981 of the '517 application is identical to SEQ ID NO: 27 of the instant application. SEQ ID NO: 144724 of the '517 application is identical to SEQ ID NO: 4 of the instant application. SEQ ID NO: 191792 of the '517 application would appear to encode at least a fragment of the same enzyme as SEQ ID NO: 4 of the instant application. SEQ ID NO: 84490 of the '517 application is identical to SEQ ID NO: 14 of the instant application. SEQ ID NO: 5431 of the '517 application is identical to SEQ ID NO: 225 of the instant application. SEQ ID NO: 240905 of the '517 application is identical to SEQ ID NO: 298 of the instant application. SEQ ID NO: 2965 of the '517 application is identical to SEQ ID NO: 311 of the instant application. SEQ ID NO: 233016 of the '517 application appears to encode the same enzyme as SEQ ID NO: 311 of the instant application. SEQ ID NO: 175329 and 241028 of the '517 application appear to encode the same enzymes as SEQ ID NO: 569 of the instant application. SEQ ID NO: 10554 of the '517 application is identical to SEQ ID NO 619 of the instant application. The '517 application and the instant application have at least two inventors in common. It is unclear if these sequences have been elected for examination in the '517 application. **An indication from Applicant as to the elected sequences in the '517 application could overcome this rejection..**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The examiner notes Applicant's request to hold these rejections in abeyance, pending a notice of allowability.

Claims 1-2 and new claims 10-21 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims drawn to polynucleotides of copending Application No. 09/262,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because the encompassed sequences are the same or equivalent as they would appear to encode the same enzymes as required by claim 1. For example, SEQ ID NO: 4513 of the '979 application is identical to SEQ ID NO: 356 of the instant application. SEQ ID NO: 4776 of the '979 application is identical to SEQ ID NO: 311 of the instant application. SEQ ID NO: 4775 of the '979 application would appear to encode the same enzyme as that of SEQ ID NO: 311. SEQ ID NO: 4761 of the '979 application is identical to SEQ ID NO: 298 of the instant application. SEQ ID NO: 4688 of the '979 application is identical to SEQ ID NO: 225 of the instant application. It is unclear whether these sequences are under examination in the '979 application. These two applications have at least two inventors in common. **An indication from Applicant as to whether these sequences are under examination in the '979 application could obviate this rejection.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The examiner notes Applicant's request to hold these rejections in abeyance, pending a notice of allowability.

Claim Rejections - 35 USC § 102

Claim 1 remains rejected and new claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by AF037030.

Paper #14 sets forth that SEQ ID NO: 14 was not disclosed in the parent provisional application. Therefore, this embodiment is granted only the instant filing date of 4/28/99. Therefore, AF037030 is a proper rejection under 102(a).

AF037030 (GenEMBL Database Record, 26 November 1998) is a disclosure of a mRNA/ cDNA sequence for a 6-phosphogluconate dehydrogenase enzyme of maize. This disclosure meets the limitations of the enzymes recited as (b) in claim 1. AF037030 has 95% sequence homology with SEQ ID NO: 14, and would clearly hybridize to SEQ ID NO: 14 under the recited conditions.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 1, 2 and 10-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *This new grounds of rejection is necessitated by Applicant's amendments.*

Claims 1 and 2 have been amended such that it is entirely unclear which SEQ ID NO: is intended to encode which enzyme. Does each SEQ ID NO: encode each enzyme? Must each polynucleotide which encodes one of the enzymes hybridize to all of the SEQ ID NO:s? Applicant should clearly amend the claims to indicate which enzyme is to be encoded by which polynucleotide comprising which particular SEQ ID NO: Claims 10-21 do not further clarify this issue.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:00 am and 1:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
11/30/01

Mary K Zeman
MARY K ZEMAN
PATENT EXAMINER
AU 1631